# **EXCLUSIVE LICENSE AGREEMENT**

AGREEMENT, dated as of February 4, 2000 (the "Effective Date"), between THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, a New York Corporation ("Columbia"), and Toev Medical Corporation, a Delaware corporation (the "Corporation").

#### 1. Definitions.

- "Affiliate" shall mean any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Corporation. Control means ownership or other beneficial interest in 50% or more of the voting stock or other voting interest of a corporation or other business entity.
  - "Field" shall mean exclusive super cooling of the brain b.
  - "Field Supplemental" shall mean exclusive super cooling of one or C. more kidneys.
- "Information" shall mean all information conveyed by Columbia to d. the Corporation relating to the technology claimed under the Patents.
- "Net Sales" shall mean the total of all fees and other consideration charged by the Corporation and any Affiliate for the manufacture, use, sale, rental, or lease of Products or Products Supplemental, less returns and customary trade discounts actually taken, outbound freight, value added, sales or use taxes, and custom duties. In the case of transfers of Products or Products Supplemental to an Affiliate by the Corporation for sale, rental, or lease of such Products or Products Supplemental to third parties by such Affiliate, Net Sales shall be based upon the greater of the total fees and other consideration charged by the Affiliate to third parties or the total fees and consideration charged by the Corporation to the Affiliate.
- "Patents" shall mean the United States patent application Serial No. 09-330,428, filed June 8, 1999 entitled "Intravascular Catheter with Pressure-Dependent Valve," and any corresponding foreign patent application or related patent document, including any provisional, divisional, continuation, continuation-in-part, substitute, renewal, reissue, extension, confirmation, reexamination or registration thereof and any patent issuing therefrom including any substitute, renewal, reissue, extension, confirmation, reexamination or registration thereof that is owned or controlled, in whole or in part, by Columbia.

- "Product(s)" shall mean a catheter or other modality to effectuate exclusive cooling of the brain, the development, manufacture, use, sale, rental or lease of which is covered by a claim of a Patent or involves the use of Information.
- "Product(s) Supplemental" shall mean a catheter or other modality to effectuate exclusive cooling of one or both kidneys, the development, manufacture, use, sale, rental or lease of which is covered by a claim of a Patent or involves the use of Information.
- "Sublicensee" shall mean any third party to whom the Corporation has granted a sublicense pursuant to this Agreement.
  - "Territory" shall mean the world. į.

#### 2. License Grant.

- Columbia grants to the Corporation, upon and subject to all the terms and conditions of this Agreement:
- (i) an exclusive license throughout the Territory under the Patents to develop, manufacture, use, sell, have sold, rent, or lease Products or Products Supplemental in the Field and the Field Supplemental;
- (ii) an exclusive license throughout the Territory to use Information to develop, manufacture, use, sell, have sold, rent, or lease Products or Products Supplemental in the Field or the Field Supplemental where such information is not in the public domain.
- Columbia grants to the Corporation the right to grant sublicenses to b. third parties, provided that (i) the Sublicensee agrees to abide by all the terms and provisions of this Agreement; (ii) the Corporation remains fully liable for the performance of its and its Sublicensees' obligations hereunder; (iii) the Corporation notify Columbia of any grant of a sublicense and provide to Columbia upon Columbia's request a copy of any sublicense agreement; and (iv) no such sublicense shall relieve the Corporation of its obligations under Section 6 hereof to exercise its own best efforts to develop and market Products or Products Supplemental throughout the Territory.
- All rights granted by Columbia to the Corporation under this Agreement are subject to the requirements of 35 U.S.C. Sections 200 et seq., as amended, and implementing regulations and policies. Without limitation of the foregoing, the Corporation agrees that, to the extent required under applicable law, any Product or Product Supplemental used, sold, rented or leased by the Corporation, an Affiliate or a Sublicensee in the United States will be manufactured substantially in the United States.

## 3. Royalties and Payment.

- a. In consideration of the license granted under Section 2(a) of this Agreement, the Corporation shall pay to Columbia:
- (i) a non-refundable license fee comprised of a) \$50,000 payable on the signing of this Agreement and b) the Shares (as defined in the Stock Purchase Agreement between Columbia and the Corporation of even date herewith (the "Stock Purchase Agreement")), issuable as specified in the Stock Purchase Agreement, and other consideration to Columbia as specified in the Stock Purchase Agreement;
- (ii) additional license fees of: a) \$50,000 upon raising \$5 million in Capital, b) \$50,000 upon raising \$10 million in Capital, c) \$100,000 upon a 510k or regulatory filing for a Product or Product Supplemental, whichever comes first, and d) \$250,000 upon receipt of 510K or U.S. regulatory approval for a Product, provided, however, that if 510K or U.S. regulatory approval for a Product Supplemental is received prior to receipt of any such approval for a Product, then a fee of \$100,000 shall be payable upon receipt of such regulatory approval for a Product Supplemental, with a license fee of \$150,000 remaining payable upon receipt of any such approval for a Product.
- (iii) a royalty of 5% of Net Sales of all Products or Products Supplemental developed, manufactured, used, rented, leased or sold where such development, manufacture, use, rental, lease or sale would, except for the license granted by this Agreement, infringe a claim of a Patent filed or issued in any country of the Territory, reduced by that amount which the Corporation is required to pay pursuant to a license agreement with a third party or parties with respect to such Net Sales, provided, however, that in no event shall any such third party be entitled to receive royalties with respect to such Net Sales at a rate higher than that to which Columbia is entitled, and provided, further, that in no event shall such royalty payable to Columbia be reduced to a rate of less than 3%;
- (iv) a royalty of 2% of Net Sales of all Products or Products Supplemental developed, manufactured, used, rented, leased or sold where such development, manufacture, use, rental, lease or sale, although not within the scope of any Patent filed or issued in any country of the Territory, involves the use of Information or technology directly derived from the technology claimed in the Patents; and
- (v) a license fee of \$75,000, payable on or before the date four years from the date of this Agreement to maintain exclusivity, subject to Section 6 hereof, in the Field Supplemental.
- b. In consideration of the right to sublicense third parties granted under Section 2(b), the Corporation shall pay to Columbia a percentage of all royalties

and other fees and consideration (including stock) received by the Corporation pursuant from its Sublicensees, according to the sliding scale below:

- (i) where the royalty rate payable by the Sublicensee to the Corporation is equal to 8% or less of the Sublicensee's net sales of Products or Products Supplemental: Columbia to receive a royalty of 4% of the Sublicensee's net sales reduced by that amount which the Corporation is required to pay pursuant to a license agreement with a third party or parties with respect to the Sublicensee's net sales, provided however, that in no event shall any such third party be entitled to receive royalties with respect to such net sales at a rate higher than that to which Columbia is entitled, and provided, further, that in no event shall the royalty payable to Columbia be reduced to a rate less than 3% of the Sublicensee's net sales:
- (ii) where the royalty rate payable by the Sublicensee to the Corporation is equal to 8% to 10% of the Sublicensee's net sales of Products or Products Supplemental: Columbia to receive 50% of the royalties payable by the Sublicensee to the Corporation, reduced by that amount which the Corporation is required to pay pursuant to a license agreement with a third party or parties with respect to the Sublicensee's net sales, provided however, that in no event shall any such third party be entitled to receive royalties with respect to such net sales at a rate higher than that to which Columbia is entitled, and provided, further, that in no event shall the royalty payable to Columbia be less than 3% of the Sublicensee's net sales;
- (iii) where the royalty rate payable by the Sublicensee to the Corporation is 10% to 20%: Columbia to receive a royalty of i) 5% of the Sublicensee's net sales plus ii) 25% of the royalties payable by the Sublicensee to the Corporation in excess of 10% of the Sublicensee's net sales, reduced by iii) that amount which the Corporation is required to pay pursuant to a license agreement with a third party or parties with respect to the Sublicensee's net sales, provided however, that in no event shall any such third party be entitled to receive royalties with respect to such net sales at a rate higher than that to which Columbia is entitled, and provided, further, that in no event shall the royalty payable to Columbia be reduced to a rate less than 3% of the Sublicensee's net sales; and
- (iv) where the royalty rate payable by the Sublicensee to the Corporation is greater than 20%: Columbia to receive a royalty of i) 7.5% of the Sublicensee's net sales plus ii) 15% of the royalties payable by the Sublicensee to the Corporation in excess of 20% of the Sublicensee's net sales, reduced by iii) that amount which the Corporation is required to pay pursuant to a license agreement with a third party or parties with respect to the Sublicensee's net sales, provided however, that in no event shall any such third party be entitled to receive royalties with respect to such net sales at a rate higher than that to which Columbia is entitled, and provided, further, that in no event shall the royalty payable to Columbia be reduced to a rate less than 3% of the Sublicensee's net sales.

#### 4. Reports and Payments.

- On or before the last business day of January, April, July, and October of each year of this Agreement, the Corporation shall submit to Columbia a written report with respect to the preceding calendar quarter (the "Payment Report") stating:
- (i) Net Sales made by the Corporation and any Affiliate during such quarter;
- (ii) In the case of transfers of Products or Products Supplemental to an Affiliate by the Corporation for sale, rental, or lease of such Products or Product Supplemental by the Affiliate to third parties, Net Sales by the Corporation to the Affiliate and Net Sales by the Affiliate to third parties during such quarter:
- (iii) Amounts accruing to, and received by, the Corporation from said Sublicensees during such quarter;
  - (iv) Net Sales by said Sublicensees during such quarter; and
- (v) A calculation under Section 3 of the amounts due to Columbia, making reference to the application subsection thereof.
- Simultaneously with the submission of each Payment Report, the b. Corporation shall make payments to Columbia of the amounts due for the calendar quarter covered by the Payment Report. Payments shall be made by check payable to The Trustees of Columbia University in the City of New York and sent to the following address: Columbia Innovation Enterprise, General Post Office, P.O. Box 29944, New York, NY 10087-9944
- The Corporation shall maintain at is principal office usual books of account and records showing its actions under this Agreement. Upon reasonable notice, such books and records shall be open to inspection and copying, during usual business hours, by an independent certified public accountant to whom the Corporation has no reasonable objection, for two years after the calendar guarter to which they pertain, for purposes of verifying the accuracy of the amounts paid by the Corporation under this Agreement.

#### Reservation of Rights for Research Purposes. 5.

Columbia reserves the right to use the Patents and Information being licensed herein for noncommercial research purposes and to permit other entities or individuals to use such Patents and Information for noncommercial research purposes. Columbia shall give the Corporation prior notice of its intent to permit other entities or

individuals to use the Patents and Information as provided herein, which shall include the identity of such entities or individuals, and shall obtain from all such entities or individuals an agreement in writing not to use the Patents or Information either outside of Columbia, or for commercial purposes.

#### 6. Best Efforts.

The Corporation shall use its best efforts to develop and market Products for commercial sale and distribution throughout the Territory, and to such end, the Corporation or its Affiliates shall achieve the following objectives within specified time periods following the date of this Agreement in accordance with the following schedule:

#### Best efforts for Products:

prototypes of 1 Licensed Product:	one year
initiate large animal tests:	18 months
initiate human clinical trials:	27 months
file a 510K or PMA	36 months
receive FDA approval	54 months
raise \$10 million (consisting of Research	
And Development Funding from a Sub-	
licensee or other third party and/or capital	
financing)	60 months
commence commercial sale of one Product	
in the U.S.	60 months
commence commercial sale of one Product	
in Europe	72 months
commence commercial sale of one Product	
in Japan	72 months

The Corporation shall use its best efforts to develop and market Products Supplemental for commercial sale and distribution throughout the Territory, and to such end, the Corporation or its Affiliates shall achieve the following objectives within specified time periods following the date of this Agreement in accordance with the following schedule:

Best efforts for Products Supplemental:

commence commercial sale of one Product Supplemental

72 months

- Milestone delay: If the Corporation fails to achieve a milestone as outlined in Section 6(a) hereof, it may delay no more than three one-year periods from the above schedule and is required to demonstrate for and prior to each one-year extension of the milestones that the Corporation has expended what Columbia reasonably considers to be acceptable research efforts, or in the alternative has spent \$1.0 million for research with respect to a Product during the 12-month period immediately prior to the deadline date applicable to the milestone. The Corporation will also pay Columbia a \$25,000 fee for each year's extension up to the three years, which shall be payable on the first business day of each such extension.
- Failure to achieve all of the objectives outlined in Section 6(a) hereof within the specified period, plus up to three one-year extensions granted pursuant to paragraph 6(c), shall result in Columbia having the option to terminate all the licenses granted hereunder with respect to Product(s) or convert such exclusive licenses to non-exclusive licenses. However, Columbia shall not have the right under this Section to terminate the exclusive license with respect to Product(s) in any country of the Territory in which the Corporation has received regulatory approval to market a Product unless the Corporation has failed to commence selling a Product in such country within one year after receipt of such regulatory approval, or as soon as is commercially practicable, whichever is later.
- Failure to achieve the objective outlined in Section 6(b) hereof within the specified period shall result in Columbia having the option to terminate all the licenses granted hereunder with respect to Product(s) Supplemental or convert such exclusive licenses to non-exclusive licenses. However, Columbia shall not have the right under this Section to terminate the exclusive license with respect to Product(s) Supplemental in any country of the Territory in which the Corporation has received regulatory approval to market a Product Supplemental unless the Corporation has failed to commence selling a Product Supplemental in such country within one year after receipt of such regulatory approval, or as soon as is commercially practicable, whichever is later.
- Failure to pay the license fee specified in Section 3(a)(v) hereof by the date specified therein shall result in Columbia having the option to convert the exclusive license granted hereunder with respect to Product(s) supplemental to nonexclusive licenses.
- The Corporation shall be deemed to have met the best efforts standard of paragraph 6(a) and 6(b) if it achieves all of the objectives of paragraph 6(a) and 6(b) above.

h. No less often than every six-month anniversary of the date of this Agreement, the Corporation shall report in writing to Columbia on progress made toward the objectives set forth above.

### 7. Patent Prosecution and Maintenance.

Columbia, by counsel it selects to whom the Corporation has no reasonable objection, in consultation with counsel appointed by the Corporation, if any, will prepare, file, prosecute and maintain all Patents in Columbia's name and in countries designated by the Corporation. Columbia and the Corporation shall use all reasonable efforts to establish the broadest possible patent coverage. The Corporation will reimburse Columbia for reasonable expenses it has incurred and will pay expenses incurred in the future in filing, prosecuting and maintaining such Patents, including reasonable attorneys' fees, the costs of any interference proceedings, reexaminations, or any other exparte or interpartes administrative proceeding before patent offices, taxes, annuities, issue fees, working fees, maintenance fees and renewal charges. Such expenses shall be reimbursed by the Corporation within 30 days after the Corporation's receipt of an invoice from Columbia, provided that the Corporation's obligations to commence reimbursement of said expenses shall be delayed until the date 6 months after the date of this Agreement.

## 8. <u>Infringement</u>.

- a. Columbia will protect its Patents from infringement and prosecute infringers at is own expense when in its sole judgment such action may be reasonably necessary, proper, and justified.
- If the Corporation shall have supplied Columbia with written evidence demonstrating to Columbia' reasonable satisfaction prima facie infringement of a claim of a Patent by a third party selling products or products supplemental in competition with the Corporation or any of its Affiliates or Sublicensees, the Corporation may by notice request that Columbia take steps to assert the Patent. Unless Columbia shall within three months of the receipt of such notice either (i) cause such infringement to terminate or (ii) initiate legal proceedings against the infringer, the Corporation, may upon notice to Columbia, initiate legal proceedings against the infringer at the Corporation's expense. In such event the Corporation may deduct from payments due hereunder to Columbia reasonable costs and legal fees incurred to conduct such proceedings, but in no event shall any payment due in any calendar guarter be reduced by more than 50 percent of the amount otherwise due to Columbia hereunder. Any recovery by the Corporation in such proceedings shall first be used to reimburse the Corporation for its reasonable costs and legal fees incurred to conduct such proceedings and next to pay to Columbia an amount equal to all amounts withheld from Columbia by the Corporation under this Section 7 during the pendency of the

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proceedings. The balance shall be divided 75% to the Corporation and 25% to Columbia.

c. In the event one party shall initiate or carry on legal proceedings to enforce any Patent against an alleged infringer, the other party shall use its best efforts to cooperate fully with and shall supply all assistance reasonably requested by the party initiating or carrying on such proceedings. The party that institutes any proceeding to protect or enforce a Patent shall have sole control of that proceeding and shall be responsible for the reasonable expenses incurred by said other party in providing such assistance and cooperation as is requested pursuant to this paragraph.

### 9. Disclaimer of Warranty.

Nothing in this Agreement shall be construed as a warranty or representation by either party as to the validity of any Patent. Nothing in this Agreement shall be construed as a warranty or representation by either party that anything developed, manufactured, used, sold, rented, leased, or otherwise disposed of under any license granted under this Agreement is or will be free from infringement of domestic or foreign patents of other parties.

# 10. <u>Prohibition Against Use of Columbia's Name</u>.

The Corporation will not use the name, insignia, or symbols of Columbia, its faculties or departments, or any variation or combination thereof, or the name of any trustee, faculty member, other employee, or student of Columbia for any purpose whatsoever without Columbia's prior written consent.

#### 11. Compliance with Governmental Obligations.

- a. Notwithstanding any provision in this Agreement, Columbia disclaims any obligation or liability arising under the license provisions of this Agreement if the Corporation is charged in a governmental action for not complying with or fails to comply with governmental regulations in the course of taking steps to bring any Product or Product Supplemental to a point of practical application.
- b. The Corporation shall comply upon reasonable notice from Columbia with all governmental requests directed to either Columbia or the Corporation and provide all information and assistance necessary to comply with legitimate governmental requests.
- c. The Corporation shall insure that research, development, and marketing undertaken by the Corporation, its Subsidiaries and Affiliates under this Agreement complies with all government regulations in force and effect including, but not limited to, Federal, state, and municipal legislation.

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## 12. Indemnity and Insurance.

- a. The Corporation will indemnify and hold Columbia harmless against any and all action, suits, claims, demands, prosecutions, liabilities, out-of-pocket costs, and expenses (including reasonable attorneys' fees) based on or arising out of this Agreement, including, without limitation, (a) the development, manufacture, packaging, use, sale, rental, or lease of Products or Products Supplemental, even if altered for use for a purpose not intended, (b) use of Patents or Information by the Corporation, its Affiliates, its Sublicensees or its (or their) customers and (c) any representation made or warranty given by the Corporation, its Affiliates or Sublicensees with respect to Products or Products Supplemental, Patents or Information. Notwithstanding the foregoing, the Corporation shall not be liable pursuant to this Section 12(a) for any incidental or consequential damages, other than any such damages awarded to a third party.
- b. Commencing no more than 20 days from the signing of this Agreement, the Corporation shall maintain, during the remainder of the term of this Agreement, comprehensive general liability insurance, including product liability insurance, with reputable and financially secure insurance carriers acceptable to Columbia to cover the activities of the Corporation, its Affiliates and its Sublicensees, for minimum limits of \$2,000,000 combined single limit for bodily injury and property damage per occurrence and in the aggregate. Such insurance shall include Columbia, its trustees, directors, officers, employees and agents as additional insureds. The Corporation shall furnish a certificate of insurance evidencing such coverage, with thirty days' written notice to Columbia of cancellation or material change.

The Corporation's insurance shall be primary coverage; any insurance Columbia may purchase shall be excess and noncontributory. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement.

The Corporation shall at all times comply with all statutory workers' compensation and employers liability requirements covering its employees with respect to activities performed under this Agreement.

### 13. Marking.

Prior to the issuance of patents, the Corporation will mark Products or Products Supplemental made, sold, or otherwise disposed of by it under the license granted in this Agreement with the words "Patent Pending," and following the issuance of one or more patents, with the numbers of such patents.

## 14. Export Control Laws

This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America which may be imposed from time to time by the government of the United States of America. Furthermore, each party hereto agrees that it will not export, directly or indirectly, any technical information acquired from the other under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

### 15. Breach and Cure.

- a. In addition to applicable legal standards, the Corporation shall be considered to be in material breach of this Agreement for (i) failure to pay fully and promptly amounts due pursuant to Section 3 and payable pursuant to Section 4 or Section 7; or (ii) failure to comply with governmental requests directed to Columbia or the Corporation pursuant to Section 11(b).
- b. Either party shall have the right to cure its material breach. The cure shall be effected within a reasonable period of time but in no event later than ninety days after notice of the breach given by the non-breaching party, provided, however, that the cure period with respect to any material breach described in Section 15(a) shall be thirty days after notice of the breach given by the non-breaching party.

### 16. Term of Agreement.

- a. This Agreement shall be effective as of the date first set forth above and shall continue in full force and effect until its expiration or termination in accordance with this Section 16.
- b. Unless terminated earlier under any provision of this Agreement, the term of the exclusive license granted under the Patents shall extend until the expiration of the last to expire of the Patents.
- c. The license granted under this Agreement may be terminated by Columbia (i) upon ninety days written notice to the Corporation if Columbia elects to terminate in accordance with Section 6(b), (ii) upon ninety days' written notice to the Corporation for the Corporation's material breach of the Agreement and the Corporation's failure to cure such material breach in accordance with Section 15(b), or (iii) should the Corporation commit any act of bankruptcy, become insolvent, file a

petition under any bankruptcy or insolvency act or have any such petition filed against it.

- d. Upon any termination of this Agreement pursuant to Section 16(c) (i) or (ii), all sublicenses granted by the Corporation under it shall be assigned to Columbia.
- 17. <u>Notices</u>. Any notice required or permitted to be given under this Agreement shall be sufficient if sent by certified mail (return receipt requested), postage pre-paid, if

to Columbia, to:

**Executive Director** 

Columbia Innovation Enterprise

Columbia University

Engineering Terrace, Suite 363 500 West 120th St., Mail Code 2206

New York, NY 10027

copy to:

General Counsel
Columbia University
412 Low Memorial Library

535 West 116th St., Mail Code 4308

New York, NY 10027

to the Corporation, to:

Dr. Arthur Schwartz 393 Gloucester Street

Englewood, New Jersey 07631

copy to:

Lawrence Obstfeld 75 Pierrepont Street

Brooklyn Heights, New York 11201

or to such other address as a party may specify by notice hereunder.

18. <u>Assignment</u>. This Agreement may not be assigned without the written consent of the other party.

19. <u>Governing Law</u>. This Agreement shall be governed by New York Law applicable to agreements made and to be fully performed in New York.

IN WITNESS THEREOF, Columbia and the Corporation have caused this Agreement to be executed by their duly authorized representatives as of the day and year first written above.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

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Name: Jack M. Granowitz

Title: Executive Director, Columbia

Innovation Enterprise

**TOEV MEDICAL CORPORATION** 

By:\_\_\_\_\_ Name: Title: 19. <u>Governing Law</u>. This Agreement shall be governed by New York Law applicable to agreements made and to be fully performed in New York.

IN WITNESS THEREOF, Columbia and the Corporation have caused this Agreement to be executed by their duly authorized representatives as of the day and year first written above.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

By:\_\_\_\_ Name:

Jack M. Granowitz

Title:

Executive Director, Columbia

Innovation Enterprise

**TOEV MEDICAL CORPORATION** 

By: <u>Awarel betfett</u> Name: Lawrence ops Held

Title: President